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| 10/030,225 | 06/27/2002 | Toshio Ota | 084335-0153 | 9216 |

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/030,225 | OTA ET AL. | |
| | Examiner | Art Unit | |
| | Rachel B. Kapust | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *2,3,11-18,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-10,19 and 20* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0802*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I (claims 1, 4-10, and new claims 19-21, drawn to polynucleotides encoding the peptide of SEQ ID NO: 2) is acknowledged. The traversal is on the ground(s) that the restriction requirement was contrary to the unity of invention standard, and all of the groups have SEQ ID NO: 2 as the special technical feature thus restriction is improper. In addition, Applicants note that the restriction requirement omitted claims 19 and 20 which were added by a preliminary amendment filed January 8, 2002.

Applicant's arguments have been fully considered but have not been found to be persuasive. Although the reasoning behind the restriction requirement dated 26 January 2004 was contrary to the unity of invention standard, the groups were restricted properly because Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1. Under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 broadly encompasses a polynucleotide comprising a protein-coding region of SEQ ID NO: 1, a polynucleotide encoding a protein comprising SEQ ID NO: 2, a polynucleotide encoding a protein that is functionally equivalent to a protein comprising SEQ ID NO: 2, and a polynucleotide encoding a partial peptide of a protein comprising SEQ ID NO: 2. NCBI Accession No. AAD09622 teaches an amino acid sequence that is 97.8% identical to SEQ ID NO: 2. Therefore, polynucleotides encoding proteins that are functionally equivalent to SEQ ID NO: 2 are not considered to be a special technical feature. Accordingly, each of the groups are not linked under PCT Rule 13.1 by a special technical feature.

Regarding Applicant's reference to Example 17 of the Administrative Instructions Under the PCT in which a claim to "protein X" and a claim to a "DNA sequence encoding protein X" were found to have unity of invention, there is no special technical feature linking the two groups. First, there is no special technical feature linking the groups because of the teachings of NCBI Accession No. AAD09622 as stated above. Second, there is no special technical feature linking the polynucleotides of Group I and the polypeptides of Group II because the

polynucleotide claims encompass antisense DNA, complements, fragments, primers, and probes which do not encode polypeptides.

As for claims 19 and 20 which were added in a preliminary amendment, these claims are drawn to a transformant comprising a vector comprising the polynucleotide of Group I and a method for producing a protein by expressing such a transformant. In the restriction requirement these claims should have been part of Group I.

Claims 21-23 are newly added. Claim 21 is drawn to a polynucleotide encoding a protein having an amino acid sequence of SEQ ID NO: 2. Claim 22 is drawn to a protein having the amino acid sequence of SEQ ID NO: 2. Claim 23 is drawn to an antibody that binds to a protein having the amino acid sequence of SEQ ID NO: 2. Claim 21 is restricted to the elected Group I. Claims 22 and 23 are drawn to non-elected inventions. Claim 22 is restricted to the non-elected Group II and claim 23 would be restricted to a new group.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The restriction requirement is still deemed proper and is therefore made FINAL. Claims 2-3, 11-18, and 22-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1, 4-10, and 19-21 are under consideration.

***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 08 July 1999. It is noted, however, that applicant has not filed a certified copy of the JP 11/194179 application as required by 35 U.S.C. 119(b).

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (please check the entire specification, but see, for example, pages 2, 3, 6, and 19). Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

The use of the trademarks ABI PRISM™ (p. 18), BIGDYE™ (p. 18), and AMPLITAQ GOLD™ (p. 22) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 5, 7, 10, and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1, 7, and 10 are drawn to polynucleotides and antisense DNA, all of which are unaltered, naturally occurring articles. Thus, they are not articles of "manufacture". These rejections may be obviated by amending the claims to read "an isolated polynucleotide" or "a purified polynucleotide" or "an isolated antisense DNA" or "a purified antisense DNA" so long as there is support for the amendment in the specification. Claims 5 and 19 are drawn to transformants comprising polynucleotide sequences or vectors. According to the specification, examples of cells that may be used as hosts for the vectors are eukaryotic cells such as COS cells and CHO cells (p. 11). As such, the claims read on cells that may be used in cloning humans. These rejections may be obviated by amending the claims to read "an isolated transformant" so long as there is support for the amendment in the specification.

Claims 5 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 5 and 19 are drawn to transformants comprising recombinant polynucleotides. Such cells may be used for cloning humans which is unpatentable. This rejection may be obviated by amending the claims to read "an isolated transformant" so long as there is support for the amendment in the specification.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-10, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a polynucleotide that hybridizes under stringent conditions with a polynucleotide comprising the amino acid sequence according to SEQ ID NO: 2. The term "stringent conditions" is a relative term which renders the claims indefinite. The term is not defined by the claim, and whereas the specification provides examples of stringent conditions (see p. 9), the specification neither provides a definition of stringent conditions nor a standard for ascertaining the requisite degree, and one skilled in the art would not be reasonably apprised of the scope of the invention. It is unclear what amount hybridizing would occur under "stringent" conditions. One skilled in the art would not know what the metes and bounds of stringent conditions are. Claims 4-10, 19, and 20 are rejected as being dependent on claim 1.

Claims 1, 4-10, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 4-10, 19, and 20 are drawn to polynucleotides encoding proteins that are "functionally equivalent" to a protein comprising SEQ ID NO: 2. The term "functionally equivalent" is a relative term which renders the claims indefinite. Neither "function" nor "equivalent" are defined by the claim, the specification does not provide a standard for determining whether or not a protein is functionally equivalent to one comprising SEQ ID NO: 2, and one skilled in the art would not be reasonably apprised of the scope of the invention. One skilled in the art would not know what the metes and bounds of "functionally equivalent" are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-10, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, does not reasonably provide enablement for polynucleotides encoding variants of SEQ ID NO: 2 wherein amino acids are replaced, deleted, inserted, and/or added, polynucleotides that hybridize to SEQ ID NO: 1, or antisense DNA against the whole or parts of fragments and variants of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention; 2) state of the prior art; 3) relative skill of those in the art; 4) level of predictability in the art; 5) existence of working examples; 6) breadth of claims; 7) amount of direction or guidance by the inventor; and 8) quantity of experimentation needed to make and/or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims encompass a large number of variants with no required common structures of functional characteristics. The problem of predicting polypeptide structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide is extremely complex. While it is known that many amino acid substitutions are generally possible in any given polypeptide, the positions within the polypeptide's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Moreover, certain positions in the sequence are critical to the polypeptide's structure/function relationship, such as various sites or regions directly involved in binding, activity, and in providing the correct three-dimensional spatial orientation of binding and active sites. Particular regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions.

Applicants have provided little or no guidance beyond the mere presentation of sequence data to enable one of skill in the art to determine, without undue experimentation, the positions in the encoded polypeptide that are tolerant to change and the nature and extent of changes that can be made in these positions. For instance, the polynucleotide comprising SEQ ID NO: 1 encodes a polypeptide consisting of 571 amino acids. Claims 1, 4-10, and 19-20 are drawn to polynucleotides encoding variants of SEQ ID NO: 2 wherein one or more amino acids are replaced, deleted, inserted, and/or deleted, polynucleotides encoding polypeptides that are functionally equivalent to a protein comprising SEQ ID NO: 2 wherein the polynucleotide hybridizes to SEQ ID NO: 1, and polynucleotides encoding partial sequences of proteins functionally equivalent to a protein comprising SEQ ID NO: 2. The only functional limitation for the polypeptides is that they are "functionally equivalent" to a protein comprising SEQ ID NO: 2. According to the specification, "a protein having activity which is at least partially equivalent to the growth and differentiation promoting activity of the protein of the present invention can be considered as functionally equivalent" (p. 7). However, one of skill in the art would not know which amino acids may be replaced, inserted, and/or deleted from SEQ ID NO: 2 in order to yield a functional equivalent of SEQ ID NO: 2. Regarding the polynucleotides that hybridize to SEQ ID NO: 1, one would not know what to do with the molecules identified by hybridization.

The claims are also drawn to polynucleotides encoding fragments of functional equivalents of SEQ ID NO: 2. The encoded polypeptides could have structures that are very different from that of SEQ ID NO: 2 with functions that are different from that of SEQ ID NO: 2. The specification provides no guidance as to which (if any) of the amino acids can be changed or deleted to yield a functional equivalent of the polypeptide comprising SEQ ID NO: 2. Even if an active site or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity.

Due to the large quantity of experimentation necessary to generate the infinite number of variants recited in the claims and screen the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide

activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on polypeptide structure and function, and the breadth of the claims which fail to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claims 1, 4-10, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a genus, *i.e.* nucleic acid molecules encoding variants of SEQ ID NO: 2. The genus includes isolated polynucleotides encoding variants of SEQ ID NO: 2 wherein amino acids are replaced, deleted, inserted, and/or added, polynucleotides that hybridize to SEQ ID NO: 1, polynucleotides encoding fragments functional equivalents of SEQ ID NO: 2, and antisense DNA against the whole or parts of fragments and variants of SEQ ID NO: 1. The claims are drawn to a genus of polynucleotides that is defined by sequence identity. Applicants have disclosed one species, the polynucleotide consisting of SEQ ID NO: 1, but have not disclosed sufficient species for the broad genus which includes polynucleotides encoding variants of SEQ ID NO: 2 wherein amino acids are replaced, deleted, inserted, and/or added, polynucleotides that hybridize to SEQ ID NO: 1, polynucleotides encoding fragments of functional equivalents of SEQ ID NO: 2, and antisense DNA against the whole or parts of variants of SEQ ID NO: 1.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. The instant disclosure of a single species of polynucleotide does not adequately describe the scope of the claimed genus, which encompasses hundreds of different polynucleotides with varying structures and functions. The instant specification fails to provide sufficient descriptive information, such as definitive structural or

functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. Structural features that could distinguish the compounds in the genus from other members of the EPO/TPO family are missing from the disclosure. Applicants are claiming a species which has not been sufficiently described, *i.e.* Applicants are claiming sequences that have not yet been identified. Only once the nucleic acid molecules have been sequenced and their functions have been determine can a person of skill in the art determine that the encoded polypeptides are functional equivalents of SEQ ID NO: 2. Thus, no identifying characteristics or properties of the instant polynucleotides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Accordingly, one of skill in the art would doubt that Applicants had possession of the claimed species at the time the application was filed.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NO: 1 is insufficient to describe the genus.

Therefore, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 7-10 are rejected under 35 U.S.C. 102(a) as being anticipated by NCBI Accession No. AAD09622 (first seen at NCBI on January 26, 1999). Claims 1 and 7-10 are drawn to polynucleotides encoding proteins that are functionally equivalent to a protein comprising SEQ ID NO: 2, polynucleotides encoding partial peptides of a protein comprising SEQ ID NO 2, primers for synthesizing such polynucleotides, probes for detecting such polynucleotides, and antisense DNA against the whole or part of such polynucleotides. NCBI Accession No. AAD09622 teaches a polypeptide sequence that is 97.8% identical to SEQ ID NO: 2. A nucleic acid sequence encoding such a polypeptide is an inherent feature of the polypeptide, as are primers and probes and antisense DNA. Thus, claims 1 and 7-10 are anticipated by NCBI Accession No. AAD09622.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over NCBI Accession No. AAD09622 as discussed above. Claims 4-6 and 19-20 are drawn to vectors comprising polynucleotide sequences as discussed above, transformants comprising the polynucleotide sequences or vectors, and recombinant methods for producing proteins or partial peptides. NCBI Accession No. AAD09622 teaches a polypeptide sequence that is 97.8% identical to SEQ ID NO: 2, however it does not teach using the encoding polynucleotide sequence in vectors or transforming cells with the polynucleotide sequence or using the polynucleotide sequence to produce proteins or partial peptides. Even so, it would have been obvious to a person of ordinary skill in the art to use the polynucleotide sequence encoding the polypeptide taught by NCBI Accession No. AAD09622 in such common recombinant DNA techniques. Such techniques are used routinely when characterizing DNA sequences. See for example Peters P. 1993, Biotechnology: A Guide to Genetic Engineering, Ed. by K. Kane, Wm. C. Brown Communications, Iowa. One would have been motivated to do so because such recombinant DNA techniques are routinely used in the laboratory and are expected to be successful for engineering expression vectors for expressing protein sequences.

***Conclusion***

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1, 4-10, 19, and 20 are rejected.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

Geddis *et al.* (2002), *Cytokine & Growth Factor Reviews* 13: 61-73

Bociek *et al.* (1996), *CA Cancer J. Clin.* 46: 165-184

Lawler (2002), *J. Cell. Mol. Med.* 6(1): 1-12

Bork (1993), *FEBS* 327(2): 125-130

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBK
5/14/04

JANET ANDRES
PATENT EXAMINER